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*Ed*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/234,532 01/21/99 SAPSE

A 1398-002

EXAMINER

008698  
STANDLEY & GILCREST LLP  
495 METRO PLACE SOUTH  
SUITE 210  
DUBLIN OH 43017

HM22/0410

OWENS JR, H	
ART UNIT	PAPER NUMBER

1623

22

DATE MAILED:

04/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/234,532

Applicant(s)  
Sapse

Examiner  
Howard Owens

Group Art Unit  
1623



☒ Responsive to communication(s) filed on Jan 25, 2001

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-3, 5, 10, 11, 13, 14, 17, and 19 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-3, 5, 10, 11, 13, 14, 17, and 19 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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*Response to Arguments/Declaration*

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/25/01 has been entered.

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**35 U.S.C. 112**

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As noted in the advisory action mailed 11/13/00 the rejection of claims 1-3, 10-11, 13-14, 17 and 19 under 35 U.S.C. 112(1) has been withdrawn based on applicant's citation of support for the instant invention as a composition in the instant specification.

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**Declaration**

The rejection of claims 1-3,5,10,11,13,14,17 and 19 under 35 U.S.C. 103 is maintained for the reasons of record set forth in the advisory action mailed 11/13/00.

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The declaration submitted states that the study supporting the beneficial results was released in May of 2000; however, other than the methodology of the experiment, the actual study or data was not provided to the examiner as factual evidence. To be of probative value, any objective evidence should be supported by actual proof; moreover, the declaration does not outweigh the evidence supporting the prima facie case of obviousness as set forth in the office actions mailed 3/2/00 and 7/21/00. The 35 U.S.C. 103 of record is not solely based upon administration of the compounds singularly, although applicant admits in p.2 of the instant reply that the specification teaches that

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the compounds may be administered separately or as "...a composition defined as having both components systemically in the human body".

As cited previously, Beale teaches the use of anti-cortisol compounds such as HMB, DHEA, Ipriflavone and phosphatidylserine in the treatment of patients with AIDS to reduce the catabolic effects associated with AIDS (col.2-col.8, line 19). Beale does not explicitly teach the use of anti-cortisol compounds in a composition with anti-HIV drugs.

Lemay et al. teach the cortisol blocker ketaconazole in combination with the anti-HIV drug Zidovudine (AZT).

Devita et al. teach that combinations of anti-HIV drugs are beneficial in treating HIV infection for several reasons: Two or more drugs may have additive or synergistic interactions that produce better efficacy than with either drug alone, lower doses than those employed in monotherapies- possibly decreasing toxicity, delaying the emergence of a resistant virus that can escape drug inhibition, and targeting of different cellular and tissue reservoirs of the virus; particularly AZT in combination with ddC, ddI or 3TC as the combination of AZT with these agents present stronger synergy over monotherapies or treatment of AZT resistant isolates (DeVita et al., AIDS, 4th edition, pp. 502-504).

The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

The prior art need not explicitly state each side effect, only provide a motivation to combine the two compounds, in this case, applicant's side effects would be viewed as catabolic effects, and given that Lemay and Devita teach the benefits of combination therapies wherein cortisol blockers are used in the treatment of HIV

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to increase the synergistic effects of an anti-HIV drug and cortisol blockers are shown by Beale to reduce the catabolic effects of the disease itself, whether the catabolic effects are associated with the use of the anti-HIV drug or the disease itself, one of skill would include cortisol blockers in the treatment regime to  
5 reduce or alleviate these catabolic effects as an adjunct to a combination therapy.

A *prima facie* case of obviousness is supported when the prior art alone would have appeared to suggest doing, at the time the invention was made, what the applicant has done. It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made that a cortisol blocker could be used in  
10 a composition with an anti-HIV drug. One of skill in the art would have been provided with a clear motivation and a reasonable expectation of success to combine the teachings of Beale with that of Lemay and Devita given that any method of treatment would seek to reduce the catabolic effects associated therein, as Lemay and Devita teach the benefits of combination therapies wherein cortisol  
15 blockers are used in the treatment of HIV to increase the synergistic effects of an anti-HIV drug and cortisol blockers are shown by Beale to reduce the catabolic effects of the disease itself, whether the catabolic effects are associated with the use of the anti-HIV drug or the disease itself, one of skill would include cortisol blockers in the treatment regime to reduce or alleviate these catabolic effects as  
20 an adjunct to a combination therapy.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Howard Owens whose telephone number is (703) 306-4538. The examiner can normally be reached on Tuesday-Friday 9 a.m.-6:30 p.m. (EST).

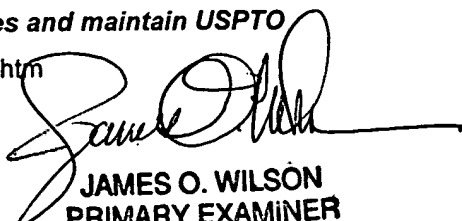
If attempts to reach the examiner by telephone are unsuccessful, Mr. Gary Geist (703) 308-1701, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

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**Applicant(s) may pay patent maintenance fees, non-filing application fees and maintain USPTO accounts** through <http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm>

  
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